



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of

CARTER et al.

Atty. Ref.: 51-575; Confirmation No. 7887

Appl. No. 10/500,613

TC/A.U. 1635

Filed: November 16, 2004

Examiner: Gibbs

For: USE OF DSRNAS IN STRATEGIC THERAPEUTIC INTERVENTION OF HIGHLY  
ACTIVE ANTIRETROVIRAL THERAPY

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**DECLARATION OF WILLIAM A. CARTER, M.D.**

I, William A. Carter, hereby declare and state as follows:

1. I am one of the co-applicants in respect of the above-identified application and that my residence is as indicated in the application papers.

2. I am the patentee of U.S. patent 4,950,652 as well as several other U.S. patents and the author of numerous articles relating, among other topics, to the treatment of HIV infections as evidenced, for instance, in my curriculum vitae, a copy of which is attached.

3. That I am familiar with the Official Action of October 10, 2006 and, in particular, the examiner's comments directed to my U.S. patent 4,950,652 and I wish to address the examiner's comments in this declaration.

4. The procedures described in my '652 patent employed various anti-retroviral agents including azidothymidine (AZT) and ribavirin as well as various other anti-retroviral products. The procedures described in my '652 patent employ, in combination, an anti-retroviral agent or agents and a DsRNA, specifically Ampligen®. According to the therapy at the time of this patent, in the early 1990s, therapy was instituted using a combination of the anti-retroviral agent(s) and was continued over a period of time until patients developed toxicity or their HIV showed resistance.

5. That according to my '652 patent, therapy was continued until the relevant end point was achieved and was not discontinued then resumed at a later point.

6. The subject application is directed to a very different situation in which an aggressive anti-viral treatment course is administered, a treatment so rigorous that significant cumulative toxicities develop, including hepatitis and pancreatitis.

7. As explained in the subject application, we have found that once HAART therapy is discontinued with a strategic therapeutic interruption (STI) beneficial results have been obtained when during this period a DsRNA administered as the sole therapeutic intervention. Then if and when HIV load increases, HAART therapy is resumed along with the continued use of a DsRNA.

8. This form of therapy differs significantly from that practiced in the late 80's and early 90's in which anti-viral therapy once instituted was continued for long periods of time and there was no strategic or other kind of planned "interruption" or "intervention" in the regimen of therapy.

9. If a person evaluating the subject application were to conclude that DsRNA therapy is basically interchangeable with any other type of anti-retroviral, this person would be mistaken. In fact, a DsRNA is an anti-viral and immune-stimulating agent which allows the control of HIV for significant periods of time (while subjects remain off HAART therapy, the "interruption"). This dsRNA "intervention" allows recovery from HAART related toxicity while controlling rebound of HIV.

10. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

DATE: 4/6/07

William A. Carter  
William A. Carter, M.D.



## Curriculum Vitae of William A. Carter, M.D.

Chairman and Chief Executive Officer  
HEMISPHERx BIOPHARMA, INC.  
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Philadelphia, PA 19103  
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### Academic Appointments:

University:  
Professor of Oncology and Hematology,  
Allegheny University Hospitals (1980-1998)

Institute:  
Director of Clinical Research,  
The Institute for Cancer and Blood Diseases

Office:  
The Institute for Cancer and Blood Diseases  
Allegheny University Hospital  
Broad and Vine  
Philadelphia, Pennsylvania 19102

### Personal and Family:

Date of Birth: February 28, 1938  
Place of Birth: Norfolk, Virginia  
Marital Status: Married

### Education and Military Experience:

1954-56 Mathew Maury High School, Norfolk, VA; Valedictorian  
1956-59 Trinity College, Duke University, Durham, NC  
1960 B.S., Chemistry, Trinity College, Duke University, Durham, NC  
1959-63 Duke University School of Medicine  
1963 M.D., Duke University School of Medicine  
1963-64 Intern, Medicine, Duke Hospital  
1964-65 Fellow, Medicine, Research Training Program Departments of Medicine and Biochemistry, Duke University  
1965-67 Senior Assistant Surgeon, U.S. Public Health Service, assigned to National Institutes of Health. Served as Research Associate, Laboratory of Biology and Viruses, Biochemistry and Biophysics Section, National Institute of Allergy and Infectious Diseases  
1967-72 Visiting Physician, Baltimore City Hospitals  
1967-68 Senior Assistant Resident, Osler Medical Service, Johns Hopkins Hospital  
1967-68 Fellow in Medicine, Johns Hopkins University School of Medicine  
1967-72 Assistant Professor of Medicine, Johns Hopkins University School of Medicine  
1968-72 Assistant Professor of Microbiology, Johns Hopkins University School of Medicine  
1968-72 Assistant Physician, Outpatient Department, Johns Hopkins Hospital  
1972-78 Chairman, Department of Microbiology, State University of New York at Buffalo, Roswell Park Division  
1972-80 Professor of Microbiology, State University of New York at Buffalo, Roswell Park Division  
1972-80 Attending Physician, Roswell Park Memorial Institute and Erie County Medical Center  
1972-80 Director, Department of Medical Viral Oncology, Roswell Park Memorial Institute

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1975-80 Professor of Medicine, State University of New York at Buffalo  
1980- Professor of Oncology and Hematology, Allegheny University Hospital  
1980- Director of Clinical Research, The Institute for Cancer and Blood Diseases  
1983-86 Senior Associate, Division of Biophysics, Johns Hopkins University

Membership in Professional Societies:

1963 Alpha Omega Alpha  
1968 American Federation of Clinical Research  
1970 American Society of Microbiology  
1972 Biophysical Society  
1972 American Association of Cancer Research  
1973 American Society of Biological Chemists  
1974 American Society for Clinical Investigation  
1974 New York State Society of Internal Medicine

Certification:

1969 American Board of Internal Medicine  
1973 Fellow, American College of Physicians

Medical Licensure:

States of New York, Maryland, North Carolina and Pennsylvania

Honors:

1960-62 Pre-Doctoral Fellow, National Foundation for Infantile Paralysis  
1969-72 Research Career Development Awardee, National Institutes of Health  
1971 Visiting Lecturer, Katholieke Universiteit te Leuven  
1972 Visiting Lecturer, Gordon Research Conference on Medicinal Chemistry  
1972 Visiting Lecturer, Austrian Academy of Biochemistry  
1972 Visiting Lecturer, Hungarian Academy of Science and Institute for Cultural Relations  
1972 Visiting Lecturer, U.S.S.R. Academy of Science  
1972 Fellow, American College of Physicians  
1978 1st NATO Advanced Studies Institute, "Antiviral Mechanisms and Control of Neoplasia," Corfu, Greece;  
(Co-Convenor)  
1978 Meadowbrook Hall Lecturer  
1979 Advances in Research Lecturer, American Cancer Society Annual Crusade (N.Y. State Division)  
1982- Advisory Board, Institute of Medical Sciences, Academia Sinica, Republic of China, Taipei, Taiwan.  
1984 Presentation before U.S. Congress on "Cancer Prevention" at Congressional Clearinghouse on the Future.

Research Interests:

Cancer Chemotherapy, Viral Chemotherapy, Biochemical Virology, Molecular Biology, Molecular Immunology.

Clinical Interests:

Cancer Chemotherapy, Infectious Diseases with Emphasis on Viral Chemotherapy

Consultantships:

- 1971 Member, Ad Hoc Committee on Antiviral Substances, National Institutes of Allergy and Infectious Diseases  
1972-88 Consultant, Cancer Centers Program, National Cancer Institute  
1973-90 Editor, Selective Inhibitors of Viral Functions (Chemical Rubber Company, Publisher); 8 printings through 1981.  
1974-80 Editorial Board, Medikon  
1975-79 Member, Developmental Therapeutics Study Section, National Cancer Institute  
1978-80 Member, American Cancer Society National Advisory Committee, Interferon Programs  
1984-88 Co-Editor, Handbook of Experimental Pharmacology on Interferon (Springer-Verlag, Publisher). 575 pages, first edition in 1984.

Scientific Publications:

Carter, W.A. and Estes, E. H. Electrocardiographic manifestations of ventricular hypertrophy: a computer study of ekg anatomical correlations of 319 cases. Amer. Heart J., 68: 173, 1964.

Carter, W.A., Becker, R.F., King, J.E. and Barry, W.F. Intrauterine respiration in the rat fetus, 11. Analysis of Roentgenological Techniques, Amer. J. Obstet. Gynec., 90: 247, 1964.

Mengel, C.E. and Carter, W.A. Geophagia diagnosed by roentgenograms. JAMA, 187: 955, 1964.

Mengel, C.E., Carter, W.A. and Horton, E.S. Geophagia with iron deficiency anemia. Cachexia Africans. Arch. Intern. Med., 114: 474, 1964.

Carter, W.A. and McMarty, K.S. The molecular loci of antibiotic action. Ann. Intern. Med., 64: 1087, 1966.

McCarty, K.S., Carter, W.A., Laszlo, J. and Parsons, J.T. Psynthetic capacities of liver nuclear subfractions. J. Biol. Chem., 421: 5489, 1966.

Friedman, R., Levy, H.B. and Carter, W.A. Replication of an arbovirus. I. forms of viral RNA. Proc. Natl. Acad. Sci. USA, 56: 440, 1966.

Carter, W.A., Levy, H.B. and Diamond, L.S. Protein synthesis by amoebal ribosomes. Nature, 213: 722, 1967.

Carter, W.A. and Levy, H.B. The interaction of mammalian ribosomes with cellular and viral RNAs. Arch. Biochem., 120: 563, 1967.

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Friedman, R.M., Fantes, K., Levy, H.B. and Carter, W.A. Interferon action on parental semliki forest virus. J. Virol, 1: 1168, 1967.

Levy, H.B. and Carter, W.A. The molecular basis of interferon action. J. Molec. Biol., 31: 561, 1968.

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Carter, W.A. Interferon: Evidence for subunit structure. Proc. Nat. Acad. Sci. USA, 67: 620, 1970.

Carter, W.A., Hande, K.R., Essien, B., Prochownik, E. and Kaback, M.M. Comparative production of interferon by human fetal, neonatal and maternal cells. Infection and Immunity, 3: 671, 1971.

Pitha, P.M. and Carter, W.A. The DEAE dextran: Polyriboninosinate-polyribocytidylate complex: Physical properties and interferon induction. Virology 45: 777, 1971.

Carter, W.A. Purification of mouse and human interferons: Detection of Subunit structures. Preparative Biochemistry, 55, 1971.

Pitha, P.M. and Carter, W.A. Antiviral activity produced by the polycytidylic acidhexainosinate system. Nature New Biology, 234: 105, 1971.

Brockman, W.W., Carter, W.A., Li, L.H., Reusser, F. and Nichol, R.F. The streptovaricins inhibit RNA dependent DNA Polymerase present in an oncogenic RNA virus. Nature, 230: 249, 1971.

Carter, W.A., Brockman, W.W. and Borden, E.C. Streptovaricins inhibit focus formation by MSV(MLV) complex. Nature New Biology, 232: 214, 1971.

Borden, E.C., Brockman, W.W. and Carter, W.A. Selective inhibition by streptovaricin of rauscher leukemia virus-induced splenomegaly. Nature New Biology, 232: 214, 1971.

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Carter, W.A., Pitha, P.M., Marshall, L.W., Tazawa, I., Tazawa, S and Ts'o, P.O.P. structural requirements of the rln.rcn Complex for induction of human interferon. J. Molec. Biol., 70:567, 1972.

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Marshall, L.W., Pitha, P.M. and Carter, W.A. Mechanisms of interferon inactivation: The effect of protonation. Virology, 48: 607, 1972.

Borden, E.C. and Carter, W.A. Viral Chemotherapy: Its promise and problems. Medicine, 51: 189, 1972.

Pitha, P.M., Marshall, L.W. and Carter, W.A. Interferon: The dissociation of rln.rCn induced proteins by protonation. J. Gen. Virol., 21: 169, 1973.

Carter, W.A. Chemotherapy of human oncogenic viral infections: The possible role of interferon and reverse transcriptase inhibitors. J. Surg. Onc., 5: 113, 1973.

Chadha, K.C., Davey, M.W., Byrd, D.M. and Carter, W.A. Differential production of interferon and refractoriness inducing principle in newcastle disease virus infected L929 cells. Infection and Immunity, 10: 1057, 1974.

Horoszewicz, J.S., Byrd, D.M., Sokal, J.E. and Carter, W.A. The colony-forming cell in the normal and leukemic host: Responses to streptovaricin and rifamycin SV. J. Nat. Cancer Inst., 52: 649, 1974.

Horoszewicz, J.S. and Carter, W.A. Responses of the murine myeloid colony-forming cell to ansamycin antibiotics. Antimicrobial Agents and Chemotherapy, 196, 1974.

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Arya, S.K., Carter, W.A., Alderfer, J.L. and Ts'o, P.O.P. Inhibition of RNA directed DNA polymerase of murine leukemia virus by 2'-O-alkylated polyadenylic acid. Biochem. Biophys. Res. Comm., 59: 608, 1974.

Carter, W.A. and DeClercq, E. Viral Infection-Host Defense: Modulatory role of double stranded RNA. Science, 186: 1172, 1974.

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Arya, S.K., Carter, W.A., Alderfer, J.L. and Ts'o, P.O.P. Inhibition of murine leukemia virus replication in cell culture and spleen focus formation in mice by polyadenylic acids. Mol. Pharmacol., 11: 501, 1975.

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Arya, S.K., Carter, W.A., Zeigel, R.F. and Horoszewicz, J.S. The search for "virogene" in human prestatic tissues: Prestatic DNA polymerases. Cancer Chemotherapy Reports, 59:39, 1975.

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- Arya, S.K., Carter, W.A., Alderfer, J.L., and Ts'o, P.O.P. Inhibition of the synthesis of murine leukemia virus in cultured cells by polyribonucleotides and their 2'-O-alkylated derivatives. Molec. Pharm., 12: 234-241, 1976.
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Mayhew, E., Papahadjopoulos, D., O'Malley, J., Carter, W.A. and Vail, WJ. Cellular uptake and protection against virus infection by poly I.Poly c entrapped within phospholipid vesicles. Molec. Pharm., 13: 488-495, 1977.

Milavetz, B.I., Horoszewicz, J.S., Evans, M.J., Manly, K.F., Rinehart, Jr., K.L. and Carter, W.A. Reverse transcription, a probe by the immobilized template poly (adenylic acid)agarose. Molec. Pharm. 13: 496-503, 1977.

Horoszewicz, J.S., Leong, S.S. and Carter, W.A. Differential susceptibility of spleen focusforming virus and murine leukemia viruses to ansamycin antibiotics. Antimicrob. Agents and Chemo., 12: 4-10, 1977.

Freeman, A.D., Al-Bussam, N., O'Malley, J.A., Stutzman, L., Bjornsson, S., Carter, W.A. Pharmacologic effects of polyinosinic-polycytidylic acid in man. J. Med Virol, 1: 79-93, 1977.

Buffett, R.F., Ito, M., Cairo, A.M. and Carter, W.A. Antiproliferative activity of highly purified mouse interferon. J. Nat. Cancer Inst., 60: 243-246, 1978.

Chadha, K.C., Sclair, M., Sulkowski, E. and Carter, W.A. Molecular size heterogeneity of human leukocyte interferon. Biochemistry, 17: 196-200, 1978.

Milavetz, B.I., Horoszewicz, J.S., Rinehart, Jr., K.L. and Carter, W.A. A study of ansamycin inhibition of an RNA-directed DNA-polymerase by an immobilized template assay. Antimicrob. Agents Chemother., 13: 435-440, 1978.

Horoszewicz, J.S., Leong, S.S., Ito, M., DiBerardino, L. and Carter, W.A. Aging in vitro and large scale interferon production by 15 new strains of human diploid fibroblasts. Infection and Immunity, 19: 720-726, 1978.

Zarling, J.M., Sosman, J., Borden, E.C., Horoszewicz, J.S. and Carter, W.A. Enhancement of cytotoxic t cell responses by purified human fibroblast interferon. J. Immunol., 121: 2002-2004, 1978.

Green, J.J., Alderfer, J.L., Tazawa, I., Tazawa, S., Ts'o, P.O.P., O'Malley, J.A. and Carter, W.A. Interaction of rIn.rCn with its interferon induction receptor: Dependence on primary and secondary structures. Biochemistry, 17: 4214-4220, 1978.

O'Malley, J.A. and Carter, W.A. Human Interferons: Characterization of the major molecular components. J. Reticuloendothelial Society, 23: 299-305, 1978.

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Horoszewicz, J.S., Leong, S., Ito, M., Buffett, R.F., Karakousis, C., Holyoke, E., Dolen, J.G. and Carter, W.A. Human fibroblast interferon in human neoplasia: Clinical and laboratory studies. Cancer Treatment Reports, 62: 1899-1906, 1978.

Heine, J.W., Mikulski, A.J., Sulkowski, E. and Carter, W.A. Stabilization of human fibroblast interferon purified on concanavalin A-sepharose. Arch. Virol, 57: 185-188, 1978.

Job, L., Carter, W.A. and Aqa, S.Y. Reverse transcriptase activity in extracts of human prostatic tissues. Oncology, 35(5): 202-205, 1978.

Mizrahi, A., O'Malley, J.A., Carter, W.A., Takatsuki, A., Tamura, G. and Sulkowski, E. Glycosylation of Interferons: Effects of tunicamycin on human immune interferon. J. Biol. Chem., 253: 7612-7615, 1978.

Arya, S.K., Job, L., Carter, W.A. and Horoszewicz, J.S. Oncornavirus-like particles released by human prostatic explant cultures. Oncology, 36: 248-253, 1979.

Chawda, R., Job, L., Carter, W.A., Horoszewicz, J.S. and Arya, S.K. Effect of bromodeoxyuridine and interferon on cellular and viral functions in human prostatic cells. Oncology, 36: 35-39, 1979.

Dolen, J.G., Carter, W.A., Horoszewicz, J.S., Vladutiu, A.O., Leibowitz, A.I. and Nolan, J.P. Fibroblast interferon treatment of a patient with chronic active hepatitis: Increased number of circulating T lymphocytes and elimination of rosette-inhibitory factor. Am. J. Med., 67: 127-131, 1979.

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